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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/770,342	FLEISCHHACKER, MARK G.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2005 has been entered.

The Examiner acknowledges that no changes to the claims are made in the Amendment accompanying the RCE. Claims 1-21 are pending.

The Examiner further notes that claims 4, 5, 14, 15, 18 and 19 were amended in the Amendment of December 2, 2002. However, claims 5, 14, 15, 18 and 19 are listed as original claims, and only claim 4 is listed as previously presented in the amendment filed August 11, 2005.

Claim Objections

2. Claim 5 is objected to because of the following informalities: in line 1, --the-- should be inserted before "core" and in line 2, "medal" should read --medial--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "the polyetherimide coating" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no polyetherimide coating recited in claims 10 or 18 prior to this recitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12, 16, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne ('640). Osborne teaches a composite guide wire shaft. Osborne teaches several embodiments for the composite guide wire shaft. *With the exception of the "hybrid" embodiment disclosed at column 5, lines 35-54,* the guide wires include a core wire that has proximal, medial and distal segments where the core wire is formed of a non-metallic, non-woven material. The core wire may be formed of a plurality of fibers chosen from a group consisting of boron fibers, carbon fibers, fiberglass, polymeric aromatic nylon fibers, silicon

carbide filaments, or the like (column 4, lines 7-11). The fibers are bonded to one another by being embedded in an adhesive matrix such that the tiny spaces between the wires are substantially filled with the adhesive (column 2, lines 44-47). The adhesive matrices can be formed of a variety of binder resins, such as epoxy resins, polyester resins, vinyl ester resin-type glues, and cyanoacrylates (column 4, lines 15-24). The core wire may be formed entirely of polymeric materials. The core wire may also be provided with an outer sleeve formed of polyethylene, Teflon ®, nylon or other suitable shrinkable material that may be provided with a hydrophilic outer coating (column 5, lines 7-20). The core wire may have proximal, medial and distal segments that have the same diameters (Figure 1) or distally tapered segments (Figure 2) that have increasing flexibility. As disclosed at column 5, lines 21-34, the core wire may include multiple, short non-metallic fibers that are "mixed" into the binder matrix. The term "mixed" implies that the fibers are randomly-disposed within the matrix and that the binder resin fills any void space between the fibers. The core wire may be provided with a helical coil on an outer surface of its distal end (column 5, lines 51-52).

7. Claims 1-11, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurtak et al. ('016). Hurtak et al. teach a glass core guide wire. The guide wire (1) includes a core wire (5) formed of a non-metallic, non-woven glass body (page 5, lines 22 and 23). Glass may be considered a polymeric material in a broad sense since it is formed by a mixture of compounds. The guide wire may be formed entirely of polymeric materials when the tip (3) is formed of plastic (page 6, line 13). A polyimide coating (6) is provided about the glass core. The a polymer sheath surrounds the coated core wire. The core wire may have proximal, medial

and distal segments that have the same diameters (Figures 2 and 3) or distally tapered segments (Figures 11-13) that have increasing flexibility.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875). Osborne, as discussed hereinabove, teaches all of the limitations of the claims except that the core wire comprises polyetheretherketone. Sirhan et al. teach that polyetheretherketone is known to be a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters to form the fibers.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Nobuhiko ('263). Osborne, as discussed hereinabove, teaches all of the limitations of the claim except that the core wire is coated with PEBAX polyethermide. Nobuhiko teaches

coating a guidewire core **1** with PEBAX polyethermide **2** to provide the guidewire with prolonged lubricating ability. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBAX polyethermide to coat a core wire similar to that of Osborne in view of the teachings of Nobuhiko in order to provide the guidewire with prolonged lubricating ability.

11. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875), and further in view of Moutafis et al. ('620).

Osborne, as discussed hereinabove, teaches a guidewire having a core wire formed of polymeric materials that is substantially completely covered with a second polymeric material. Osborne teaches all of the limitations of the claims except that polyetheretherketone and polyetherimide are used as the polymeric materials for construction.

Sirhan et al. teach that polyetheretherketone is known as a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters.

Osborne, as modified by Sirhan et al., teach all of the limitations of the claims except that the core wire is coated with polyetherimide. Moutafis et al. teach a plastic coated medical guidewire where a core wire is coated by a polyetherimide sleeve **14** (col. 3, lines 61-65) which is further coated with a hydrophilic lubricous coating **20** (col. 4, line 33). It would have been

obvious to one having ordinary skill in the art at the time applicant's invention was made to coat a polyetheretherketone a core wire similar to that of Osborne as modified by Sirhan et al., with a polyetherimide jacket and a lubricous coating in view of the teachings of Moutafis et al. as a design choice, merely selecting conventional polymeric materials to construct a guidewire that are known to provide a guidewire with steerability, flexibility, resistance to kinking and stiffness, and lubricity.

Response to Arguments

12. Applicant's arguments filed August 11, 2005 have been fully considered but they are not persuasive.

Applicant contends that Osborne clearly discloses interwound or "woven" fibers 13 and 14 as being critical components of the guidewire of Osborne and cites Figure 1 and the top of page 4 of the Osborne patent to support this argument. This argument is not persuasive.

The word "woven" is defined by The American Heritage Dictionary® of the English Language (1992) to mean constructed by interlacing or interweaving strands of material or made by winding in and out. The helically wound fibers of the Osborne patent are formed by *winding first fibers in one direction around an axis and then cross-winding second fibers over top of the first fibers in an opposite direction* (see Figure 1 and column 3, lines 42-46 and 56-65). The Examiner respectfully submits that such a configuration does not fall within the definition of "woven." Although Applicant points to the top of column 4 to support his argument, the Examiner respectfully points out that this same except of the Osborne patent states that these are "*other variations*" to the composite guide wire and that it is merely *possible* to interweave the

cross wound fibers in some fashion. Neither of these statements indicate that woven fibers are a critical component of the Osborne patent as Applicant alleges.

The Examiner further notes that line 2 of claim 1 recites "the core wire *substantially comprising* a non-metallic, non-woven, material." The transitional phrase "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03. Therefore, in the embodiment of the core wire of Osborne illustrated in Figure 1, the longitudinally disposed non-woven fibers 12 may be considered to anticipate this limitation of the claim, while the fibers 13 and 14 form the additional, unrecited elements. In view of the foregoing, the rejections citing Osborne are maintained.

The Examiner notes that all of Applicants arguments are directed to the "non-woven" limitation of the present invention. Such a limitation only occurs in claim 1 of the instant application, and the claims that depend therefrom, in the claims as filed on August 11, 2005. Therefore, Applicant has failed to provide clear arguments with respect to independent claims 10 and 19 and the claims that depend therefrom. In view of the foregoing, the rejections of these claims as set forth in the Final Rejection of September 9, 2004 have been maintained and will not be addressed further in this Office Action.

A new rejection with respect to claims 1-11, 16 and 17 under 35 U.S.C. 102(b) citing Hurtak et al. is set forth hereinabove in order to expedite prosecution of the instant application. Hurtak et al. teach a guide wire having a core wire with distal, medial and proximal segments where the core wire is formed of a non-metallic, non-woven glass material.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 30, 2005